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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,493	09/28/2001	Joseph Luber	MCP-0274	5286

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants Amendment and Response filed on April 8, 2003 and Information Disclosure Statement filed on May 29, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, 10, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuca et al. (US 5494681). Cuca teaches a pharmaceutical delivery system comprising an active agent, a wax material and a hydrophobic polymer material (Col. 2, lines 33-60). The active agent can be selected from the group consisting of antitussives, antihistamines, decongestants, alkaloids, mineral supplements, laxatives, anti-cholesteralemic, antiarrhythmics, antipyretics, appetite suppressants and expectorants (Col. 3, line 7 – Col. 4, line 8). The active agent is present from about 5% to about 65% (Col. 4, lines 9-14). The wax of the composition has a melting point from

about 5° C to about 200° C (Col. 4, lines 24-29). The wax material can be a long chain fatty hydrocarbon, animal wax, vegetable wax, petroleum wax, synthetic wax, beeswax, lanolin, stearic acid, candelilla wax, carnauba wax, microcrystalline wax, carbowax and mixtures thereof (Col. 4, lines 38-47). The wax material is present in the matrix in amounts of about 10% to about 95% (Col. 4, lines 30-36). The polymer material is a hydrophobic material that has some solubility in the wax material (Col. 4, line 48 – Col. 5, line 2). The matrix may further comprise additives and excipients such as sweetening agents, colorants, surfactants, flavors, fragrances, pH modifiers and bulking agents (Col. 5, lines 3-10). Further, Cuca contemplates immediate release systems (Col. 3, lines 7-19).

Cuca does not expressly teach the exact concentration ranges for the active agents and the wax material. Cuca does teach ranges that overlap the ranges recited in the instant claims. Cuca further does not expressly teach the particle sizes of the wax material prior to preparing the composition. Cuca does teach the particle sizes of the particles after preparation to be 10 microns to 400 microns (Col. 6, lines 31-46).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a pharmaceutical delivery system wherein the composition comprises an active agent, a wax material and a polymeric material wherein the active agent is present in amounts of at least 60%, the wax is present in amounts up to 20% and the polymer is hydrophobic in nature.

One of ordinary skill in the art would have been motivated to do this to produce a taste-masking delivery system for active agents that possess a bitter taste.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuca et al. (US 5494681) in view of McCabe et al. (US 5098715). Cuca does not expressly teach the inclusion of an outer coating.

McCabe teaches a sweetened or flavor coating for tablets (Col. 2, line 53 – Col. 3, line 48). The coating comprises hydroxypropyl methylcellulose, propylene glycol and a flavor and/or sweetener (Col. 4, line 41 – Col. 5, line 35). The coating is applied to tablets cores that contain an active agent (pseudophedrine hydrochloride) that has an unpleasant taste (Col. 3, lines 53-63). The flavored coating of McCabe also provides a pleasant tasting advantage even if the core tablet itself is neutral-tasting and does not have an objectionable taste (Col. 3, line 67 – Col. 4, line 2).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to add an outer coating to a tablet formulation that includes a sweetener or flavoring agent. Cuca teaches a tablet core that includes an active agent

that has an unpleasant taste (e.g., pseudophedrine hydrochloride). McCabe teaches a coating for tablets that contain active agents that have objectionable tastes.

One of ordinary skill in the art would have been motivated to do this to mask the unpleasant taste of the active agent of the tablet core.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuca (US 5494681) in view of Conte et al. (US 5681583). Cuca does not expressly teach the tablet formulation to have an insert containing a second drug with a different release profile.

Conte teaches a tablet that has two distinct release profiles wherein one layer releases one drug immediately and a second layer releases a second drug over a prolonged period of time (Col. 3, lines 4-32). The active agents such as ketoprofen, piroxicam and antihistamines can be carried in the two-layer tablet (Col. 4, lines 6-42).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a tablet formulation that contains two different active agents that have different release profiles. Cuca teaches a tablet formulation that can contain one or more drugs in a matrix formulation. Conte teaches a two-drug tablet formulation in which one drug is release rapidly or immediately and a second drug is releases over and extended period of time. It is the position of the Examiner that the concentration of the second drug is not critical because the effective amount of the drug to be administered will vary depending on the drug that is chosen.

One of ordinary skill in the art would have been motivated to do this to administer a drug that needs to act immediately as well as administering a drug over a prolonged period of time at a specific hematic level.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed April 8, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art teaches the use of a melted wax, while the claimed invention employs powdered wax.

It is the position of the Examiner that the prior art teaches a tablet composition comprising the same components as the instant claims, an active agent, a wax material and a hydrophobic polymer material. The Examiner fails to see the criticality is the form of the wax. The prior art and the instant claims recite the same product with the same expected results. It is the position of the Examiner that these are limitations that would be routinely determined by one or ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of the some unusual and/or unexpected results. The results must be those that accrue form the specific limitations.

Further, the difference between the prior art and instant claims appears to be a process or method difference, meaning the difference is the wax is melted in the prior art. The Examiner would like to respectfully point out that the instant claims are drawn to composition claims. Therefore, the examination of the application focuses on the composition not the process of making the composition. The prior art teaches a

composition with the same components and therefore renders the instant claims obvious.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
June 9, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600